UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUISIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF VERMONT, THE COMMONWEALTH OF VIRGINIA, and THE STATE OF WASHINGTON *ex rel.* JULIE LONG, Plaintiffs, v. JANSSEN BIOTECH, INC., Defendant.	Civil Action No. 16-CV-12182-FDS

PLAINTIFF RELATOR JULIE LONG'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT JANSSEN BIOTECH, INC.'S MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Plaintiff relator Julie Long seeks to recover, on behalf of the United States and 27 States (the "Plaintiff States"), the large sums that Janssen Biotech, Inc. ("Janssen") has defrauded from Medicare and Medicaid through a kickback arrangement it has with doctors around the country who operate in-office infusion suites and are top purchasers of Janssen's drugs Remicade and Simponi ARIA ("ARIA"). And as detailed in her Second Amended Complaint ("SAC"), Janssen regularly provides these physicians valuable, free practice management and infusion business support to induce the physicians to buy and infuse more Remicade and ARIA to patients, including Medicare and Medicaid beneficiaries. As part of the scheme, the physicians submit false bills for the drugs and related infusion services to Medicare and Medicaid that are not reimbursable because the treatments and bills violate the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and Plaintiff States' anti-kickback statutes cited in ¶24[1] of the SAC. Janssen knows that these valuable gifts are corruptive and induce sales. It also knows that, in order to get paid for the drugs and related infusions, the doctors falsely certify to Medicare and Medicaid that their bills comply with the federal and state anti-kickback statutes.

Congress enacted the AKS to outlaw corruptive schemes, like the one alleged here, that cause doctors to make decisions based on improper financial incentives rather than what is most appropriate for patients and to ensure Medicare and Medicaid do not bear the costs of such decisions. *See U.S. ex rel. Banigan v. PharMerica, Inc*., 950 F.3d 134, 137 (1st Cir. Feb. 19, 2020). As a result, providers must certify in every bill submitted to Medicare or Medicaid that it complies with the AKS. And a request for payment that resulted from an AKS violation is a per se false claim under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729, and its state

[1] All paragraph "¶" references herein are citations to paragraphs of the SAC.

analogues. *See* 42 U.S.C. § 1320a-7b(g); *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019).

As the SAC explains, Janssen's scheme also harms unsuspecting Medicare and Medicaid beneficiaries who receive recurring infusions of Remicade or ARIA while Janssen influences their doctors with the alleged gifts. Janssen is disregarding the patients' best interests by illegally inducing the physicians to purchase and infuse Remicade and ARIA—both of which are "black box" drugs because of the accompanying risks of serious infections and malignancy—instead of other drugs that may be safer, more effective, less expensive, and/or can be taken at home.

Janssen has filed a motion to dismiss under Fed. R. Civ. P. 12(b)(6) and 9(b) raising three primary factual and legal arguments. For the reasons stated below, Janssen's arguments are legally incorrect and raise factual issues that cannot be resolved on a motion to dismiss.

II. SUMMARY OF FACTUAL ALLEGATIONS

Remicade is a biologic drug approved for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and other autoimmune diseases. ¶45. Developed as Remicade's replacement, ARIA is a biologic drug approved for the treatment of rheumatoid arthritis, psoriatic arthritis, and other autoimmune diseases. ¶52. Both drugs are administered by infusion that can be performed at doctors' offices, hospitals, infusion centers, or at home (by mobile providers). ¶¶46, 53, 154. Other drugs have been approved to treat the conditions Remicade and ARIA are approved to treat. ¶¶68, 80, 87, 94. Some are administered by infusion, and some are taken by self-injection or pill. ¶¶71, 82, 88, 95. Remicade treatment generally involves a two-hour infusion every eight weeks for extended periods or, for some, life. ¶46. ARIA infusions are usually 30-minutes every eight weeks. ¶53.

Providers who perform drug infusions often purchase the drugs and then, after the infusion, bill insurers for both the drugs and infusion service. ¶¶99-101. Because insurers',

including Medicare's and Medicaid's, reimbursement rates are normally higher than the acquisition cost, physicians who buy and then bill for the drugs earn a profit (or spread) on each vial of medicine infused. ¶100. Physicians charge a fee for each infusion. ¶¶108-13. Providers do not receive any fees or payments when they prescribe drugs that are self-administered. ¶116.

The largest market for Remicade and ARIA sales is rheumatology and gastroenterology practices that operate an in-office infusion suite, which Janssen calls an "IOI." ¶118. Since at least 2003, one of Janssen's main strategies for growing the IOI market and sales of Remicade and ARIA is to advise the physician owners of the practices about how these drugs offer a lucrative business opportunity, which Janssen touts as the "infusion business model" and "Remicade model." ¶¶118-20. To allay physicians' concerns regarding the complexities, risks, and time commitments associated with starting a new infusion business, Janssen assures the doctors it will help them establish the IOIs and afterwards help operate and grow the IOIs. ¶121.

Janssen employs a large team of highly trained medical practice advisers to serve as the dedicated business partners to physicians who commit to the infusion business model and open IOIs. ¶122. Janssen calls this special team of employees "Area Business Specialists," or "ABSs" for short, and advises practices that the close attention and assistance from these business specialists are free of charge. *Id.* Each Remicade and ARIA sales territory has an ABS in addition to the customary sales representatives and medical science liaisons. ¶¶124-25. Janssen also pays business consultants, such as Xcenda, with expertise in medical practice and infusion business management to provide business advisory services to select IOI accounts. ¶¶135-38. These free business consulting services are part of the package of services Janssen provides to ensure top IOI accounts remain committed to the infusion/Remicade business model. ¶¶123-30.

To reward the accounts in each territory that purchase and infuse the highest volumes of

Remicade and ARIA and to induce these "Remicade mills" and "cash cows," as Janssen calls them, to maintain and grow their use of the drugs, ABSs visit the accounts at least monthly—and in most cases multiple times a month—to provide free practice management services that help their infusion businesses. ¶¶153, 161-63, 175. Accounts in lower tiers that do not purchase and infuse as much Remicade or ARIA receive free services but not as frequently as top accounts. ¶¶161, 188. Janssen typically does not provide these gifts to doctors who prescribe but do not infuse the drugs or who have an IOI but do not perform many infusions. *Id.* By ensuring that top accounts' IOIs are a major profit center, Janssen has created a strong economic incentive for the physician owners to continue purchasing and infusing drugs, including Remicade and ARIA. ¶¶150, 161. And by becoming an integral part of the success of their IOIs, Janssen has secured access to the doctors as well as their loyalty and desire for additional business support, causing the doctors to generally favor Remicade and ARIA over competing drugs. ¶¶151-52.

As evidenced by the job summaries quoted in ¶¶127-29, ABSs' functions include "mentor[ing] doctors and staff on how to develop and implement an In Office Infusion program including overall operations management, scheduling, staffing, pre-authorization, reimbursement, capacity management, inventory management, and infusion management/ efficiencies," "provid[ing] proactive, total account management to targeted accounts with a focus on site of care specific infusion issues, practice management and selling at an executive level," "serv[ing] as a resource to territory's accounts regarding practice management," "educating practices on appropriate efficiency practice to infuse the pharmaceutical product(s) to remain viable," and "articulating the value proposition for the customer." The SAC collectively refers to the range of services ABSs and outside consultants regularly provide to top IOI accounts as "practice management" and "business advisory services." Janssen also offers product support to

physicians and patients, such as assistance with coverage, reimbursement, and administration of Remicade and ARIA. However, as the SAC specifically advises in ¶166(r) n.14, Relator only asserts claims based upon the practice management and business support services provided to physicians with IOIs. To clearly distinguish this ***business support*** from the types of ***product support*** addressed in the OIG guidance, court rulings, and advisory opinions Janssen cites in its motion, Relator collectively refers to the services at issue here as "Infusion Business Support."

Relator, who provided the Infusion Business Support for Janssen for 13 years (¶16), describes in significant detail the wide variety of practice management and infusion business advice Janssen regularly provides to select IOI accounts. ¶¶118-76. For example, she describes how Janssen helps physicians open IOIs. ¶¶139-44. She describes how Janssen assists doctors in maintaining and growing their IOIs and also helps with issues related to their practice as a whole. ¶¶145-75. Relator describes many of the Infusion Business Support areas ABSs and the outside consultants assist with, including describing some of the presentations they utilize. ¶166. In its motion, Janssen discusses a few slide decks that ABSs use, but there are many others. Their very title shows the ***Area Business Specialists***' purpose − they are kickbacks personified. Tellingly, Janssen's motion avoids any reference to its team of employees at the center of this case.

III. ARGUMENT

A. The SAC Sufficiently States A Claim For AKS Violations

The AKS makes it illegal to, among other things, "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase … [or] order … or recommend purchasing … or ordering [of] any … service or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B).

Congress added the term "remuneration" to the AKS in 1977 to broaden the law, which earlier referred only to kickbacks, bribes, and rebates, to "cover the ***transferring of anything of value in any form or manner whatsoever***." Medicare & State Health Care Programs: Fraud & Abuse - OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991) (emphasis added). The AKS is implicated when one purpose of the kickback was to generate business payable by Medicare or Medicaid. *See U.S. ex rel. Westmoreland v. Amgen, Inc*., 812 F. Supp.2d 39, 47 (D. Mass. 2011). As the OIG has guided, "liability under the [AKS] ultimately turns on a party's intent," and "a lawful purpose will not legitimize a payment that also has an unlawful purpose." OIG Compliance Program Guidance for Pharm. Mfrs. ("2003 OIG Guidance"), 68 Fed. Reg. 23731, 23734 (May 5, 2003). In a document from a 2014 ABS training program, Janssen warned of the AKS's broad applicability: "[the AKS] [m]akes it illegal for pharmaceutical manufacturers to give [health care providers] anything of value to induce them to prescribe or purchase products that are reimbursed in whole or part by a federal health care program." ¶204.

The SAC alleges every element of an AKS violation: (1) Janssen is providing physicians valuable gifts – *i.e.,* Infusion Business Support (¶¶177-85); (2) it is providing these payments in kind to induce physicians to purchase and infuse Remicade and ARIA to Medicare and Medicaid beneficiaries (¶¶186-88); and (3) it is doing so knowingly and willfully (¶¶194-210). Further bolstering the allegations' plausibility, the OIG has identified "free training … in such areas as management techniques" as a "suspect incentive arrangement." OIG Special Fraud Alerts, 59 Fed. Reg. 65372, 65376 (Dec. 19, 1994). In addition, numerous factors set forth in the 2003 OIG Guidance that courts have identified as hallmarks of an illegal arrangement are present here. Specifically, Janssen's alleged kickback arrangement: (1) interferes with and skews physicians' clinical decision-making (¶¶9-11, 131, 156-60, 191-93); (2) increases the risk of overutilization

and inappropriate utilization (*id.*); (3) raises patient safety concerns (*id.*); (4) increases costs for Medicare, Medicaid, and patients (¶¶10, 57-8, 189-93); (5) involves physicians who have direct influence on generating business for Janssen (¶¶120-23, 143-44, 152-54, 166, 176); (6) takes into account the volume of Remicade and ARIA sales (¶¶149, 161); and (7) is "more than trivial in value" (¶¶128, 163-66, 172-73, 176-85). *See* 2003 OIG Guidance, 68 Fed. Reg. at 23734, 23737.

Also, since the Infusion Business Support constitutes "payments in kind or gifts" to select doctors, the OIG's test for this type of kickback applies. *See* OIG Special Fraud Alerts, 59 Fed. Reg. at 65376. All three OIG factors are present. The gift or payment in kind (*i.e.*, Infusion Business Support) is: (1) "made to a person in a position to generate business for the paying party"; (2) "related to the volume of business generated"; and (3) "more than nominal in value."

B. The SAC Sufficiently Alleges That Janssen Paid Valuable Kickbacks To Physicians

1. The Infusion Business Support Has Substantial Value

In her detailed summary of Janssen's illegal kickback scheme, including nine paragraphs devoted to the remuneration's value (¶¶177-85), Relator describes the Infusion Business Support in sufficient detail to allow the Court to recognize the services' substantial value. For example, the SAC explains the business risks and complexities associated with opening and operating an IOI. ¶¶121, 132, 140-41, 145, 166, 176. The SAC likewise explains in ¶¶145-48 how, through the Infusion Business Support, Janssen reduces physicians' financial risks related to operating an IOI. It describes the demand and appreciation physicians have for the Infusion Business Support, including a letter written by a physician about the ABS services Relator provided. ¶¶164-65, 172, 176(a), 177-85. It also describes the significant impact these services have on the recipients' infusion businesses (¶¶143, 153, 164), and, in ¶176, provides examples of physicians for whom Relator directly helped build, manage, fix, and grow IOIs. The SAC describes how Janssen's

hands-on assistance with opening and then supporting IOIs, although applicable to all infusion drugs and the operation of the entire practice, generates brand and infusion loyalty and causes the physicians to rely upon Janssen's ABSs. ¶¶144, 152, 155, 163-64, 172, 176. And in addition to other facts that manifest the value of the Infusion Business Support, the SAC discusses how integral and successful this corruptive kickback strategy has been in making Remicade and ARIA two of the top expenses for Medicare. ¶¶8-10, 49, 57, 156, 194, 201.

As stated in ¶182, it would defy business and common sense for Janssen to incur the significant recurring expenses associated with employing the large team of well-compensated ABSs and outside consultants for over 15 years if the recipients, Janssen's most important customers, did not value the services and the services were not generating sales of Remicade and ARIA. Moreover, that there is a paying market for the types of practice management and business advisory services Janssen provides belies Janssen's contention that the value of the Infusion Business Support is trivial, or even insubstantial. ¶¶132-38, 179-80.

Based on the SAC's detailed allegations, it is well beyond plausible that the value of the alleged Infusion Business Support is more than trivial or nominal. *See* 2003 OIG Guidance, 68 Fed. Reg. at 23737; OIG Special Fraud Alerts, 59 Fed. Reg. at 65376; *see also U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp.3d 772, 808-09 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018) (refusing to dismiss AKS claims involving gifts of customized office supplies because they are "easily distinguished from goods that have been found to be of nominal value"). Janssen itself, in a 2014 document, warned that some of the very practice management and business advisory services at issue constitute kickbacks. ¶¶203-07.

2. Janssen's Attempts To Degrade The Value Of The Infusion Business Support Are Inappropriate At This Stage And, In Any Event, Have No Merit

It bears emphasis that, although Janssen provides the types of services that OIG and

courts have labeled "product support," Relator purposefully does not allege any claims based on those services. The nature, character, and purpose of the ***business support*** services at issue here are fundamentally different than, and easily distinguished from, the ***product support*** services that drug manufacturers sometimes offer to help with coverage, reimbursement, and proper use of its products by patients. Unlike the ***business support*** at issue here, services that OIG has classified as ***product support*** do not raise the red flags of an illegal kickback arrangement identified in the 2003 OIG Guidance and OIG Special Fraud Alerts discussed in § III.A above.

Nor can it be said that the Infusion Business Support is required for proper use of Remicade and ARIA. These are business services provided by practice management consultants, not clinical training for providers or patients. And the business information and advice are equally applicable to competing infusible drugs and, for that matter, oftentimes non-infusion drugs and services. ¶¶127-28, 140, 166, 172-73, 183-84. Further demonstrating that the Infusion Business Support is not product support, Janssen does not offer the services to all physicians, only those it selects. ¶¶161, 188(b)-(c). Many of these physicians have been operating their IOIs, or "Remicade mills," for years and thus already know how to administer and bill for Remicade.

In arguing that the Infusion Business Support does not constitute remuneration under the AKS, Janssen relies almost entirely on OIG guidance, court decisions, and advisory opinions in which the remuneration at issue was "product support." None of the authorities it cites involve services that even remotely resemble the business support at issue here. For instance, Janssen cites to *U.S. ex rel. Forney v. Medtronic, Inc.*, No.15-cv-6264, 2017 WL 2653568 (E.D. Pa. June 19, 2017) where the relator alleged that a cardiac device manufacturer violated the AKS by offering: (1) free surgical support for implantation of its devices; (2) free post-implant device checks (interrogations) for patients to ensure the devices were functioning properly; and (3) free

assistance with seeking reimbursement for its devices from insurers. *See Forney* at *1-2. Applying the 2003 OIG Guidance for product support services[2], the court found that the complaint did not allege the level of detail required by Rule 9(b) to allow a finding that the product support services had "some substantial independent value" to physicians. *Id.* at *4.

In its discussion of *Forney*, Janssen fails to mention that, after the complaint's subsequent amendment, the court found that it sufficiently alleged that the product support services were illegal remuneration. *See Forney*, Order - ECF No.52 (Aug. 14, 2017). Notably, although the court voiced uncertainty as to whether that relator could prove that the product support services had independent value, it nevertheless construed the allegations in the relator's favor and allowed the case to proceed to discovery, reasoning that the issues raised in the motion to dismiss were better suited to disposition on a full factual record. *See id*.

Janssen's reliance on *U.S. ex rel. Suarez v. AbbVie Inc.*, No.15-cv-8928, 2019 WL 4749967 (N.D. Ill. Sep. 30, 2019) is likewise misplaced, as that case also involved product, not business, support. That relator alleged that the manufacturer of the self-injectable drug Humira arranged for nurses called "Ambassadors" to educate patients who were prescribed Humira about: (a) how to self-inject Humira; (b) safe disposal of the injection pens; (c) their disease state; and (d) obtaining insurance coverage. *See id.* at *2. The Ambassadors also spoke with

[2] The 2003 OIG Guidance, 68 Fed. Reg. at 23735, provides, in relevant part:

> Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have ***no substantial independent value*** to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having ***no independent value*** (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. (Emphasis added).

doctors about questions patients raised about Humira and to tout the service's benefits. *See id.* The court held that the complaint did not sufficiently explain how these product support services had independent value to physicians or patients. *See id.* at *7-10.[3]

Janssen incorrectly contends that the Infusion Business Support does not save physicians from incurring a necessary expense. Although this factor is irrelevant to payments in kind or gifts, like the Infusion Business Support, Janssen's argument fails to consider the sizable fees that physicians pay to receive similar advice (¶¶132-38, 179-80) as well as the time and overhead costs physicians save by allowing Janssen to help them open the IOIs, identify and resolve operational issues, and operate the IOIs more efficiently and profitably (¶¶140, 166, 173).

Janssen's reliance on OIG Advisory Opinions 00-10, 08-20, and 12-20 is also unavailing. Each opinion involves product support that the OIG found, under the unique scenarios presented, had no independent value. *See* Adv. Op. 00-10 (2000) (drug company offered all patients and physicians reimbursement and insurance coverage assistance for its drug; notably, OIG advised that if this support was offered in tandem with other programs that reduced physicians' financial risks associated with the drug then the arrangement would violate the AKS); Adv. Op. 08-20 (2008) (supplier had an arrangement with hospitals under which supplier's employees provided CMS-mandated education at the hospitals to patients who opted to obtain respiratory equipment from supplier); Adv. Op. 12-20 (2012) (county hospital offered all physicians free access to an electronic portal through which they could order and receive lab results from the hospital). While it does not involve product support, Advisory Opinion 08-05 (2008) is also far afield. There the OIG found that information patients printed from kiosks given to doctors by a drug company was

[3] Claims related to other product support, such as travel kits, completed prior authorization forms, and dedicated terminals that print insurance forms for Humira, were summarily dismissed due to the relator's failure to respond to the arguments concerning these items. *See id.* at *4-6.

no different than general health pamphlets commonly available in doctors' office waiting rooms.

It must be highlighted that Janssen never sought an advisory opinion for the Infusion Business Support. ¶33. Making matters worse, in boldly—and futilely—relying upon these advisory opinions that involve entirely different services, offered under entirely disparate circumstances, Janssen disregards the OIG's express instructions in each opinion that they have "no application to, and cannot be relied upon by, any other individual or entity" and "may not be introduced into evidence by a person or entity other than [the requesting party] to prove that the person or entity did not violate … [the AKS] or any other law." *E.g.*, Adv. Op. 12-20.

3. Even Under The OIG's Product Support Standard, The Infusion Business Support Constitutes Actionable Remuneration

As an initial matter, Janssen materially misstates the standard that the OIG has applied to "product support," asserting it as a two-pronged test of (1) substantial value, and (2) independent value, but this standard finds no support in the 2003 OIG Guidance or in any court decisions. Such a standard would be inconsistent with Congress's well-recognized intent that the AKS "cover the transferring of anything of value in any form or manner whatsoever," 56 Fed. Reg. at 35958. Janssen's attempt to narrow and weaken the AKS should be rejected.

However, even if the Court were to classify the Infusion Business Support as "product support" and apply Janssen's unsupported version of the OIG standard, Relator, as demonstrated above, has alleged numerous facts that considered together show that it is well beyond plausible that the Infusion Business Support has both independent and substantial value.

Janssen's contention that the Infusion Business Support has no independent value is the exact opposite of what the SAC alleges. As the SAC makes clear, the Infusion Business Support focuses on the management and operation of IOIs and the overall physician practice, not an individual infusible drug. And it is likewise clear from the SAC's descriptions of the Infusion

Business Support that the advice is non-branded (not product specific); rather it can be—and is—used by the select physician practices who receive the services to increase their efficiency and profitability on other infusible drugs as well as other drugs and services. ¶¶127-28, 140, 166, 172-73, 183-84. Moreover, because Janssen only offers the Infusion Business Support to select accounts, it is not the type of product support that can be said to be included in the drugs' cost. Finally, even if a particular presentation Janssen uses or topic it advises about is ultimately found to be product support that has "no substantial independent value," that particular service is provided "in tandem with" numerous other presentations and services that "confer[] a benefit" on the physicians – an illegal combination under the 2003 OIG Guidance, 68 Fed. Reg. at 23735.

4. The Individualized Business Support That Janssen Provides And The Slide Decks It Uses Are Not Freely Available On The Internet Or Elsewhere

At the outset, Janssen fails to cite any court decision, or even an advisory opinion, holding that individualized, in-person consultative services regarding practice management and maximizing profits on IOIs provided by consultants with expertise as well as intimate knowledge of the physicians' business, as a matter of law, are only of nominal value if some of the information presented is available on the Internet.[4] In any event, the individualized Infusion Business Support that ABSs and outside consultants provide to select physicians in person, as well as the slide decks used in connection with some of those services, are not available on the Internet. The ABSs have long-standing, personal relationships with the physicians and staff to whom they provide individualized business advice. Janssen, in complete disregard of the SAC's allegations and the very information and assistance it pays ABSs and the outside consultants to

[4] Janssen's lack of support for this ridiculous assertion is evidenced by its reliance on OIG Advisory Opinion 07-16 (2007), which involves valueless, basic information about home-based convalescence provided to patients on a videotape, not valuable, in-person business consulting.

deliver to its best customers, incredibly tries to portray the ABSs' and outside consultants' role as merely handing out copies of CMS and American Medical Association articles about a few practice management topics. Janssen would not pay the ABSs and consultants the compensation it does merely to hand out articles. ¶182. And Janssen would not tie ABSs' compensation to growth in their accounts' Remicade and ARIA sales (¶¶126, 188(d)) if ABSs were merely tasked with making valueless presentations. Nor would busy doctors and their staff regularly request and carve out large blocks of time to listen to presentations about information they could easily obtain from the Internet. ¶178. Lastly, if physician practices could easily identify, diagnose, and resolve all their IOI and practice management issues with a few Google searches, then why is demand for health care consultants and lawyers so strong?

Along with its motion, Janssen submitted slide decks related to just seven topics among the large universe of practice management and infusion business areas about which Janssen advises top accounts. For instance, Janssen ignores the "iBiz" (short for "Infusion Business Review") and "Infusion Optimization Modeler" presentations, which are described in detail in ¶166(a)-(b). It ignores the "Why IV" and "Considerations for Proactive Practice Management" presentations described in ¶¶140 and 160(b) and (h). It likewise left out the presentation ABSs and consultants use while advising practices on negotiating higher reimbursement rates for all regularly billed drugs and services. ¶166(d). Importantly, while ABSs use these and many other presentations, the Infusion Business Support that they provide extends far beyond the information in the slide decks; they help implement the advice and strategies discussed in the presentations and assist with many other issues for which there are no presentations. ¶¶167, 172.

The few slide decks that Janssen submitted, many of which postdate Relator's tenure, are neither incorporated by reference in the SAC nor central to its claims. *See Freeman v. Town of*

Hudson, 714 F.3d 29, 36-37 (1st Cir. 2013) (discussing the "narrow exceptions" when extrinsic documents can be considered in reviewing a motion to dismiss). Likewise, the various articles it submitted to try to dispute and degrade the value of these slide decks have no place in a motion to dismiss. Even if they could be considered at this stage, the only thing that the slide decks conclusively show is that operating an IOI is far more complex than Janssen contends and that the presentations relate to business support, not support of a specific product.

C. The SAC Sufficiently Alleges That Janssen Acted Knowingly And Willfully

To act "knowingly" under the AKS, a defendant must "do something voluntarily ... do it deliberately ... not do something by mistake or accident or even negligently," and to act willfully, it must "do something purposely, with the intent to violate the law ... do something purposely that law forbids." *U.S. v. Bay State Amb. & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989); *accord Bryan v. U.S.*, 118 S.Ct. 1939, 1946-47 (1998) ("[T]he willfulness requirement ... does not carve out an exception to the traditional rule that ignorance of the law is no excuse; knowledge that the conduct is unlawful is all that is required."); *U.S. ex rel. Banigan v. Organon USA Inc.*, No.07-cv-12153-RWZ, 2016 WL 10704126, at *3 (D. Mass. Aug. 23, 2016).[5] Likewise, the AKS specifically provides that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

Although Relator is only required to allege scienter generally, *see* Fed. R. Civ. P. 9(b), and the AKS does not require a specific intent to violate the statute, the SAC nevertheless pleads facts that create a strong inference that Janssen knows that providing the Infusion Business Support to select IOI accounts is unlawful. Relator details in eight paragraphs (¶¶203-10) how

[5] The Plaintiff States' anti-kickback statutes differ in their scienter requirements. *See, e.g.*, Tex. Hum. Res. Code § 32.039(a)(4) (solely requiring that the defendant act "knowingly").

Janssen has been acting not only in direct contravention of the warnings concerning the AKS set forth in its own internal compliance document from an ABS training program, but also in violation of the relevant prohibitions in the Code on Interaction issued by PhRMA, a trade group of which it is a member. Janssen's knowledge that its kickback arrangement is unlawful is also evidenced by the lengths to which it has gone to conceal it from others. ¶170.[6]

As explained in § III.A above, Janssen's arrangement with IOI accounts contains all the AKS violation hallmarks identified in the OIG guidance. And Janssen's reliance on inapposite OIG advisory opinions and court decisions only strengthens the already strong inference that it is knowingly and willfully flouting the AKS. Moreover, Janssen's feigned ignorance of the statute is disproved by the fact that, while providing the kickbacks at issue, Janssen and its affiliates have resolved claims regarding multiple other kickback schemes, including the claims alleged in *U.S. ex rel. Lisitza v. Johnson & Johnson*, No.07-cv-10288-RGS (D. Mass.) and related cases. *See* Press Release, U.S. Dept. of Justice (Nov. 4, 2013) (avail. at https://www.justice.gov/opa/pr -/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations).

Not only does Relator allege specific facts that show Janssen is acting knowingly and willfully in violating the AKS, but she also alleges that Janssen provides the Infusion Business Support to IOI accounts ***for the purpose of inducing them to prescribe and infuse Remicade and ARIA to patients, including Medicare and Medicaid beneficiaries***. ¶¶8, 126, 118-31, 150-56, 166, 176, 186-88. Indeed, the frequency and level of the Infusion Business Support that physicians receive is based upon their Remicade and ARIA sales volume. ¶¶122, 135-37, 161,

[6] Janssen cites to *Suarez* to suggest that Relator's allegations concerning its efforts to keep the kickback arrangement a secret from others cannot be construed as evidencing knowing and willful intent. Yet it fails to note that in *Suarez* the court found that allegations of efforts to hide the Ambassador program were belied by the fact that the defendant advertised the service on its website. *See* 2019 WL 4749967, at *14. Here, Janssen did not advertise the alleged kickbacks.

166, 187(b)-(c). Relator also describes how Janssen seeks purchase commitments in connection with the Infusion Business Support. ¶¶161, 167, 176(e) and (o). Additionally, she explains how Janssen ties ABSs' compensation to growth in Remicade and ARIA sales by their respective accounts. ¶¶126, 188(d). And Relator reports how Janssen's management closely monitors the scheme. ¶¶194-200. Accepting these allegations as true, it is well beyond plausible that Janssen knows that helping top IOI accounts open, operate, and grow their infusion business is unlawful.[7]

D. The SAC Satisfies The Pleading Standards Of Rule 9(b)

At the end of its brief, Janssen contends, in conclusory fashion, that the SAC fails to satisfy Rule 9(b). However, applying the First Circuit's most recent directives regarding the appropriate Rule 9(b) assessment in *U.S. ex rel. Nargol v. DePuy Ortho., Inc*., 865 F.3d 29 (1st Cir. 2017), *cert. denied*, 138 S.Ct. 1551 (2018), which Janssen apparently overlooked, the SAC easily passes muster. As *Nargol* requires, Relator's allegations lead to a strong inference that it is beyond possible that physicians across the country who receive Janssen's Infusion Business Support have submitted false bills for Remicade and ARIA to the government health care programs throughout the lengthy periods they have been benefitting from the alleged kickbacks.

The First Circuit has directed that to satisfy Rule 9(b) it is generally expected that a FCA complaint provide some essential details concerning some of the alleged false claims. *See id.* at 38-39. The First Circuit, however, recognizes that when plaintiffs allege that the defendant caused third parties to submit the false claims, as Relator alleges here, a "more flexible" 9(b)

[7] Relator has also sufficiently alleged a knowing violation of the FCA, which broadly defines "knowingly" as "actual knowledge," "deliberate ignorance," or "reckless disregard" that a claim is false. 31 U.S.C. § 3729(b)(1)(A). In addition to the allegations summarized above, Relator also alleges that Janssen knew that the doctors to whom it provided the kickbacks billed Medicare and Medicaid for Remicade or ARIA purchases and related infusions. ¶¶166-67, 176, 201-02.

standard must be applied. *Id.* To satisfy the more flexible 9(b) standard, a complaint must allege the details of a fraudulent scheme with "reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 39-41 (quoting *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009)). For instance, "a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility.'" *Id.* at 39 (quoting *Duxbury* at 29). In assessing whether a complaint states the circumstances of the alleged fraud with sufficient particularity, the First Circuit also considers whether it explains "the who, what, where, and when" of the alleged false representations, colloquially known as "the first paragraph of any newspaper story" test. *See id.* at 40.

As the SAC explains, the physicians seek payment from Medicare and Medicaid for Remicade or ARIA infusions while receiving the Infusion Business Support and therefore falsely certify in each bill that the infusions were provided in compliance with the AKS. ¶¶44, 189-93.[8] To provide additional particularity, at ¶¶176 Relator describes some of the business support services she provided to nine top IOI accounts (A to I) that Relator knows, based on her regular analyses of their prescribing practices and primary insurers/payers (¶¶166, 201-02), were billing Medicare and Medicaid for Remicade or ARIA and related infusions throughout the period she served as their personal ABS. What's more, Relator pleads the specific number of Remicade infusions billed to Medicare by physicians from several of these IOI accounts (Physicians A-1, B-1, B-2, C-1, C-2, D-1, D-2, H-1, I-1) in 2012 through 2016 while Relator regularly provided them Infusion Business Support. ¶192. Relator also pleads the volume of ARIA infusions Physician H-1 billed to Medicare in 2015 and 2016 while the physician regularly received the

[8] Since providers, not patients, bill for Remicade and ARIA, concerns noted in other cases about whether patients in fact billed Medicare for the drugs they were allegedly prescribed as a result of fraud do not exist here. *See, e.g., U.S. ex rel. Rost v. Pfizer*, 507 F.3d 720, 732 (1st Cir. 2007).

alleged kickbacks. ¶193. And to further demonstrate that Janssen's fraudulent scheme causes false claims to be submitted to Medicare, Relator describes a Medicare beneficiary (B-1) who was prescribed and administered Remicade infusions every eight weeks by physicians from Account B while Relator was regularly providing the alleged kickbacks to the account. ¶191.

That Relator did not publish the physicians' names should not lead to dismissal. Janssen, which knows who receives the alleged kickbacks, did not ask for the names.[9] Nonetheless, if the Court believes the names are essential to its Rule 9(b) assessment, Relator can provide them via an affidavit or amendment. If necessary, Relator can also identify IOI accounts in other parts of the country that received the Infusion Business Support along with their personal ABSs.

In addition to pleading data evidencing the submission of false claims, Relator pleads the alleged false claims' ***who*** (select physicians with IOIs – *e.g.*, Accounts A to I and Physicians A-1, B-1, B-2, C-1, C-2, D-1, D-2, H-1, I-1 (¶¶118-23, 176)), ***what*** (acceptance of the Infusion Business Support that renders false the representations in bills submitted to Medicare and Medicaid that the Remicade and ARIA purchases and infusions complied with the AKS (¶¶44, 189-93)), ***when*** (since approximately 2003 (¶¶38, 118, 182, 192-93)), and ***where*** (Janssen provides the alleged kickbacks at top IOI accounts around the country – *e.g.*, Accounts A to I; Remicade and ARIA infusions are administered at the accounts; and the physicians at these accounts submit false bills to Medicare and Medicaid (¶¶5, 124, 127-29, 143, 161, 176, 192-93)).

[9] Attorney Michael Maya's certification in the motion to dismiss that "[he] conferred with counsel for Plaintiff-Relator Julie Long, and we have attempted in good faith to resolve or narrow the issues presented in this motion" is false. The parties never discussed any contention Janssen made in its motion. The parties' communications concerning the motion were limited to an email Ms. Tremont sent to Relator's counsel on March 17 stating, "[f]or the purposes of our Local Rule 7.1 certification, we assume that you do not consent to the motion, but please let us know if we are mistaken or further discussion would be productive," and Relator's counsel's reply that stated "[a]s you expected, we do not consent to Janssen's motion to dismiss." Relator's counsel asked Janssen's counsel to correct the misleading certification. They declined to do so.

Relator also pleads national Medicare data showing that, from 2013 to 2017 during the alleged scheme, doctors prescribed and infused Remicade to an average of 58,641 beneficiaries annually, and that each year Medicare reimbursed the doctors, on average, $21,105 per beneficiary (or $6.1 billion over the five-year period). ¶49. Similarly, Relator reports prescription data showing that, from 2006 to 2018, doctors wrote nearly 400,000 prescriptions for Remicade infusions to beneficiaries of the Plaintiff States' Medicaid programs, and that the Plaintiff States reimbursed over $1 billion in the aggregate for the drug. ¶50. She pleads similar data regarding ARIA. ¶¶57-58. Inasmuch as the SAC alleges facts showing that Janssen provided the Infusion Business Support to select IOI accounts around the country (¶¶124, 127-29, 143, 161, 176, 192-93), and this market infuses the highest quantity of Remicade and ARIA (¶118), a strong inference can be drawn that many of the bills underlying the above data were submitted by doctors who received the alleged kickbacks. These allegations together with the SAC's detailed descriptions of the purpose and scope of the alleged kickback scheme lead to a strong inference that physicians around the country have submitted false claims to Medicare and Medicaid.[10]

In summary, Relator pleads the fraud—based on her 13 years of first-hand experience—in vivid detail, describing reliable evidence that demonstrates her allegations are sincere and that the alleged kickback scheme is much more than possible. The SAC satisfies Rule 9(b).

IV. CONCLUSION

For the foregoing reasons, the Court should deny Janssen's motion to dismiss.

REQUEST FOR ORAL ARGUMENT

Relator respectfully requests oral argument.

[10] In *Nargol*, the First Circuit found that one false claim example led to a strong inference that it was beyond possible that false claims were submitted to Medicare nationwide. *See* 865 F.3d at 41. And in *Duxbury*, an AKS case against Janssen's predecessor, the First Circuit held that allegations about false claims submitted by eight hospitals in the same state created a strong inference that false claims were submitted to Medicare nationwide. *See* 579 F.3d at 29-32.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing. Paper copies will be sent to those indicated as non-registered participants.

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